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POLICY

Voluntary Public

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GAIN Report Number: IN8002

India

Post: New Delhi

Additional List of Permissible Import of Specialty Foods with Labels

Report Categories:

Sanitary/Phytosanitary/Food Safety

Exporter Guide

FAIRS Subject Report

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Report Highlights:

The Food Safety and Standards Authority of India published an additional list of specialty food products and their labels that can be imported to treat infants and children suffering from special medical conditions.

General Information:

DISCLAIMER: The information contained in this report was retrieved from FSSAI's website <http://www.fssai.gov.in/>. The Office of Agricultural Affairs and/or the U.S. Government make no claim of accuracy or authenticity.

The Food Safety and Standards Authority of India (FSSAI) published an order to revise its permissible list of specialty foods and their labels. FSSAI, through this order, has also instructed its Authorized Officers to issue a no-objection-certificate (NOC) for such products as per the present procedure of food import clearance and frequently asked questions (FAQs) issued recently.

The FSSAI order along with the Annexures is pasted below. Readers can also access them from FSSAI's website at: <http://www.fssai.gov.in/home/imports/order-guidelines.html>

F.No. Stds/Nutra-IEM/FSSAI-2016 (Pt. F2)
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety and Standards Act, 2006)
FDA Bhawan, Kotla Road, New Delhi – 110002

Dated, The ~~28th~~ December, 2017

Notice

Subject: Import of Specialty foods for IEM disorders -Reg.

1. This is with reference to the direction issued under Section 16 (5) of Food Safety and Standards Act, 2006 dated 02nd November, 2016 regarding import of specialty foods for IEM disorders.
2. In continuation to the notice dated 12th June, 2016 regarding list of Specialty foods for IEM disorders permitted for import (Annexure II) an additional list of products permitted for import with labels is annexed (Annexure-I). For issuing NOC/NCR for the consignments of these products, the Authorized officers are advised to follow present procedure of food import clearance and FAQs issued in this regard. For better control of these products, the import shall be permitted through Delhi and Mumbai ports only.

This issues with the approval of the Competent Authority.



S.K. Yadav
Director, Imports
FSSAI HQ, New Delhi

Enclosures: as above

To

1. The Authorised Officer, Delhi.
2. The Authorised Officers, Mumbai.

Copy to:

1. PPS to Chairperson, FSSAI- for information.
2. PS to CEO, FSSAI- for information.
3. Sh. Zubair Riaz, Director (Customs), Ministry of Finance- with a request to circulate to all officials of Customs Department working as Authorised Officers.
4. The Authorised Officer, Cochin- for information.
5. The Authorised Officer, Tuticorin- for information.
6. The Authorised Officer, Chennai- for information.
7. The Authorised Officer, Kolkata- for information.

Annexure-I

Label No.	Product name	Remarks
M/s Nutricia International Pvt. Ltd.		
1	Milupa MSUD 2 prima	Allowed with stickering on the label*
2	Anamix infant MSUD	
3	Anamix infant GA1	
4	Milupa HOM 2 prima	
5	Anamix infant HCU	
6	Milupa LEU 2 prima	
7	Anamix infant IVA	
8	Milupa OS 2 prima	
9	Energivit E	
10	Milupa PKU 2 prima	
11	Milupa UCD 2 prima	
12	Milupa TYR 2 prima	
13	Anamix infant TYR	
14	Milupa LYS 2 prima	
15	Anamix infant NKH	
16	Neocate Junior chocolate	
M/s Abbott Healthcare Pvt. Ltd.		
17	Elecare Jr (for ages 1 and up) vanilla flavor#	Allowed with stickering on the label*
18	Ele care (0 - 12 months)#	
19	Tyrex - 1**	
20	Similac isomil 1 (0 - 6 months)	
21	Similac isomil 2 (6 to 12 months)	
22	Similac total comfort optigro (birth to 12 months)	
23	Similac total comfort Intelli pro 2 (for after 6 months)	

*** Copies of the labels enclosed**

Products already in the approved list for import. These are additional labels differing in design without differing in composition.

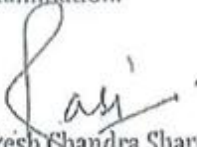
**Revised label.

Dated, the 02 Nov, 2016

Subject: Direction under Section 16(5) of Food Safety and Standards Act, 2006 regarding import of specialty foods for IEM disorders - reg.

1. Inborn Errors of Metabolism (IEM) and Hypoallergenic conditions are special medical conditions which requires specialty foods. Such specialty foods are not readily available in the country. The hospitals need these specialty foods for the management of infants and children suffering from such conditions.
2. These specialty foods are globally available. However, in the absence of Standards for such foods, it is difficult to import them into India. FSSAI has been receiving representations from various organizations for allowing these foods in the country.
3. And whereas, taking these issues into consideration, the Scientific Panel of FSSAI on "Functional Foods, Nutraceuticals, Dietetic Products and Other Similar Products" has initiated work on for setting the Standards for these products. However, it is likely to take long time to finalize these Standards in view of the complexity of this subject. Taking note of the seriousness of the issue, the Scientific Panel has, therefore, recommended that import of these products may be permitted by FSSAI for two years or till their Standards are developed and notified, whichever is earlier. The Panel, after careful consideration, recommended for allowing the import of foods for fifteen "Inborn Errors of Metabolism" and two Hypoallergenic conditions as per the Annexure.
4. It has been decided to allow the import of foods for special medical purposes, as listed in the Annexure to this Order, for a period of two years or till their Standards are developed and notified, whichever is earlier, under the following conditions:
 - a. The importing firm would submit to FSSAI well in advance, all the necessary documents related to the composition, label and claims for the product they intend to import. FSSAI after due examination, would allow the import of such foods on a case to case basis for a period of two years from the date of this Order or till their Standards are developed and notified, whichever is earlier. Once a particular composition, label & claims is permitted by FSSAI for import, future consignments strictly adhering to the requirements can be imported on the basis of this one time permission.
 - b. The labels on these foods shall clearly mention the medical conditions for which they have to be used.
 - c. The importer/manufacture of such foods shall ensure that they are consumed only under supervision of health care professionals.

5. The above conditions shall also apply to domestically produced specialty food products for which FSSAI shall grant permission after due examination.


Rakesh Ghandra Sharma
Director (Imports)

Enclosure: as above

To

1. Sh. Zubair Riaz, Director (Customs), Ministry of Finance
2. All Commissioners of Food Safety
3. All Authorized Officers, FSSAI
4. All Central Licensing Authorities of FSSAI

Copy for information to:

1. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI
3. All Directors, FSSAI.

Inborn Errors of Metabolism (IEM) and Hypoallergenic conditions

S. No	Medical condition	Description
A. IEM Conditions		
1.	Maple syrup urine disease	Isoleucine, Leucine and Valine free diet powder
2.	Glutaric Acidemia Type I	Lysine and Tryptophan free diet powder
3.	Homocystinuria	Methionine free diet powder
4.	Isovaleric Acidemia, 3-Methylcrotonyl-CoA, Carboxylase Deficiency, 3-Methylglutaconyl-CoA, Hydratase Deficiency	Leucine free diet powder
5.	Methylmalonic Acidemias, Propionic Acidemia	Isoleucine, Methionine, Threonine and Valine free diet powder
6.	Amino acid metabolic disorders	Protein and amino acid free diet powder (with and without fat)
7.	Phenylketonuria (PKU)	Phenylalanine free diet powder
8.	Urea Cycle Disorders, Argininemia, Argininosuccinic Aciduria, Carbamoylphosphate Synthetase Deficiency I, Citrullinemia	Non-essential amino acid free diet powder
9.	Tyrosinemia	Phenylalanine and Tyrosine free diet powder
10.	Galactosemia	Galactose free formula
11.	3-Hydroxy Long Chain Acyl-CoA Dehydrogenase Deficiency	LCHAD Deficiency
12.	Defects in the intraluminal hydrolysis of fat; defective mucosal fat absorption; defective lymphatic transport of fat	Milk protein-based powder with medium-chain triglycerides (MCT) for children and adults
13.	Disaccharidase deficiencies; Disorders of carbohydrate metabolism Sucrase/ isomaltase deficiency, Fructose Intolerance	Protein hydrolysate formula base powder with iron for use with added carbohydrate.

14.	Non-ketotic Hyperglycinemia, Lysinuric protein intolerance	Protein free formula
15.	Glucose transport defect(Glut1 def), Pyruvate dehydrogenase complex deficiency	Low carbohydrate, sucrose, fructose, sugar free formula
B. Hypoallergenic Conditions		
1	Severe allergy due to multiple food protein intolerance that cannot be effectively managed by extensively hydrolyzed formula	Amino acid based Hypoallergenic formula
2	Severe allergy due to intact milk protein & soya protein	For Cow's milk allergy Hypoallergenic Formula